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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,423	03/23/2001	Henrik Christian Hansen	P66431 US0	7477

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EXAMINER

KIDWELL, MICHELE M

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 07/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

N.K.

Office Action Summary

Application No.

09/787,423

Applicant(s)

HANSEN ET AL.

Examiner

Michele Kidwell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3-4</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 5, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

See MPEP § 2173.05(d).

With reference to claim 7, the applicant claims that the catheter set preferably has a broader container part. The examiner finds this language to be indefinite since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. The language raises a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –



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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 – 4 and 6 – 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Israelsson et al. (WO 97/26937).

With respect to claim 1, Israelsson et al. (hereinafter "Israelsson") discloses a catheter set comprising a catheter (3) and a package (1) wherein an elongated part of the package forms a tube (figure 1), the catheter comprises a proximal part (page 12, lines 11 – 12) and a sealing part (the protrusion immediately adjacent reference character 16 in figure 1), characterized in that the catheter further comprises a distal part in the form of a flexible tubular section (16) having an inner diameter at least as large as the inner diameter of the proximal part of the catheter wherein the sealing part is separating the proximal part of the catheter and the tubular distal part and wherein the length of the flexible tubular distal part is at least long enough to occupy the elongated part of the package as set forth in figure 1.

The examiner contends the inner diameter of the flexible tubular section is at least as large as that of the proximal part of the catheter because the flexible tubular section is a flared portion (page 12, lines 1 – 5 and figure 1) with respect to the remainder of the catheter thereby providing an inner diameter that would at least be as large as the remainder of the catheter. Likewise, the length of the flexible tubular part is at least long enough to occupy the elongated part of the package because the flexible tubular part comprises a length as shown in figure 1 and any length would be long enough to occupy an elongated part of the package.



With reference to claim 2, Israelsson discloses a catheter set characterized in that the proximal part of the catheter has a hydrophilic coating as set forth on page 11, lines 3 – 6.

With respect to claim 3, Israelsson discloses a catheter set characterized in that the set comprises a wetting fluid integrated into the package as set forth on page 18, lines 12 – 13.

As to claim 4, Israelsson discloses a catheter set characterized in that the tubular distal part of the catheter has an inner diameter larger than the inner diameter of the proximal part of the catheter as set forth in figure 1.

The examiner contends the inner diameter of the flexible tubular section is larger than the proximal part of the catheter because the flexible tubular section is a flared portion (page 12, lines 1 – 5 and figure 1) with respect to the remainder of the catheter thereby providing an inner diameter that is larger than the inner diameter of the proximal part of the catheter.

Regarding claim 6, Israelsson discloses a catheter characterized in that the tubular part is transversely corrugated as set forth in figure 1. The examiner contends that the very tip of the tubular part may be considered as the transversely corrugated portion of the tubular part.

With reference to claim 7, Israelsson discloses a catheter set characterized in that the package has an elongated narrow part at the end where the catheter exits the package (2) and a broader container part (12) as set forth in figure 1.



Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5 and 8 – 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Israelsson as applied to claims 1 – 4 and 6 – 7 above, and further in view of Daignault, Jr. et al. (US 6,053,905).

The difference between Israelsson and claim 5 is the provision that the tubular part is made from an extrudable, mouldable material.

Daignault, Jr. et al. (hereinafter “ Daignault ”) teaches a catheter wherein the made from an extrudable, mouldable material.

It would have been obvious to one of ordinary skill in the art to modify the tubular part of the catheter of Israelsson to employ an extrudable, mouldable material because the use of such a material is well known in the art as taught by Daignault in col. 3, lines 11 – 13 and allows for the flexibility to maneuver the catheter into position.

Regarding claim 8, Daignault teaches a catheter set characterized in that the package is provided with one or more sealing devices (14,16) on the exterior side of the package as set forth in figure 1.

As to claim 9, Daignault teaches a catheter set characterized in that the sealing device comprises an adhesive sheet adhered to the package as set forth in col. 3, lines 23 – 33.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Kidwell whose telephone number is 703-305-2941. The examiner can normally be reached on Monday - Friday, 7:30am - 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on 703-308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.


Michele Kidwell
June 20, 2003


WEILUN LO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700